PUNCTURE SITE CLOSURE DEVICE

RELATED APPLICATIONS AND CLAIMS OF PRIORITY

[0001] This application claims priority to, and incorporates by reference in its entirety, co-pending United States patent application number 10/086,318, filed March 1, 2002, entitled "Laparoscopic Port Site Fascial Closure Device".

BACKGROUND OF THE INVENTION

[0002] Laparoscopic, endoscopic, and thorascopic surgeries are well-known surgical techniques that advantageously reduces patient recovery time due to minimal tissue damage, which consequently permits the patient to return to normal activity in a shorter period of time. Generally, surgery relies upon the formation of one or more trocar puncture wounds through which are deployed surgical instruments and a rod-like telescope with a light source to enable the surgeon to view the organs and conduct the surgery.

[0003] Notwithstanding the tremendous advantages afforded by such surgical techniques, there still presents substantial clinical problems. More specifically, the puncture wounds created within the body by the surgeon to gain access to the surgical site are often difficult and time-consuming to close, and can place great demands on the surgeon. Such task is made even more difficult when such surgery is performed upon obese patients where there is a relatively deep puncture wound formed through a relatively small puncture site or incision. Indeed, the puncture site frequently needs to be enlarged following the procedure to ensure that the site is closed at the interior body cavity wall. Ironically, the need to enlarge the puncture site in order to adequately close the same partially negates the primary advantages of this kind of surgery; however, such practice is essential insofar as

failure to properly close the puncture wound can lead to serious medical complications.

[0004] To address such shortcomings, numerous attempts have been made to develop instruments capable of quickly and effectively forming a closure of a fascial defect, or puncture site. Exemplary of such attempts include those devices disclosed in United States Patent No. 5,741,279, issued to Gordon et al., on April 21, 1998, entitled Endoscopic Suture System; United States Patent No. 5,374,275, issued to Bradley et al., on December 20, 1994, entitled Surgical Suturing Device and Method of Use; United States Patent No. 5,964,773, issued to Greenstein on October 12, 1999, entitled Laparoscopic Suturing Device and Suture Needles; United States Patent No. 5,403,329, issued to Hinchcliffe on April 4, 1995; and United States Patent No. 5,507,757, issued to Sauer et al. on April 16, 1996, entitled Method of Closing Puncture Wounds, the teachings of all of which are expressly incorporated herein by reference.

[0005] Such attempts, however, have proven less than satisfactory and fail to provide a practical solution to the foregoing problems. In this regard, substantially all such devices allegedly designed to facilitate the closure of a laparoscopic, endoscopic, or thorascopic puncture site are incapable of deploying a suture a sufficient distance about the puncture site to fashion an appropriate closure. In this respect, prior art devices, such as those referenced above, are operative to stitch a suture into position at points diametrically across the puncture site; however, such suture typically only extends thereacross by a limited distance, which is less than 1.0 cm. In the case of laparoscopic surgery, such limited distance fails to sufficiently approximate the peritoneum and fascia surrounding the puncture site sufficiently to form an adequate closure. While it is recognized that a suture extending a greater distance across the puncture site would be more advantageous, the capability of

prior art devices position such a suture have not heretofore been available insofar as any fascial closure device must necessarily be insertable through a small endoscopic port, which may be a 10 mm laparoscopic port, which places considerable spacial constraints on the design of such devices.

[0006] Additionally disadvantages with such prior art closure devices include the failure of such devices to selectively deploy needles for positioning and stitching a suture across the puncture site that can ultimately be withdrawn from the puncture wound without the need to enlarge the incision or puncture site. Among those devices possessing such defect include those disclosed in United States Patents No. 5,964,733 and 5,403,329, referenced above, which deploy needles that, after having been deployed to fix a suture in position across an intra-abdominal puncture site, are inoperative to become repositioned within the device deployed thereby to thus atraumatically withdraw such needles from the patient.

[0007] Accordingly, there is a need for such a device that is capable of being deployed through a small diameter port or puncture site that is further capable of deploying a suture at a sufficient distance across the periphery of the puncture to gather tissue and effect a secure closure of the fascial puncture site. There is additionally a need for such a device that is capable of deploying a suture across a puncture, incision, or wound that provides for the retraction and capture of needles utilized to secure such suture in position back within the device deployed thereby to thus enable the needles to be easily and atraumatically withdrawn from the sutured puncture wound.

BRIEF SUMMARY OF THE INVENTION

[0008] The present invention is directed to a device that is operative to fashion a secure closure of incisions and puncture wounds in fascia and organ tissues. According to a preferred embodiment, the device comprises a needle/suture

complex and a cannula or other hollow tubular member having proximal and distal ends, the latter being configured to be inserted within the body via punctures or incisions used to perform laparoscopic, endoscopic, thorascopic and other such procedures. The cannula or trocar is sized to be inserted through a puncture site in need of closure or suture by the needle/suture complex.

[0009] More particularly, this device is useful for fashioning a closure of a puncture site in tissue using a cannula and connecting rod disposed within the cannula, which has an actuating mechanism formed to selectively advance or retract within the cannula, together with a needle/suture complex mounted upon the connecting rod. The connecting rod is operatively transitional between multiple configurations of a needle trap mechanism disposed within the lumen of the cannula. The needle trap mechanism preferably lockingly engages with the needles of the needle/suture complex to draw the needles into the lumen of the cannula, such that the device may be drawn from the body with the suture extending between said needles, forming a closure of the puncture site.

[0010] Preferably, disposed within the cannula, and more particularly the distal end thereof, is a needle/suture complex consisting of two diametrically-opposed needle members having an elongate suture extending therebetween that are operatively transitional from a first insertion configuration, whereby the needles are confined within the distal-most end of the cannula for insertion through the abdomen to the puncture site; a second operative configuration whereby the needle members extend outwardly from the distal-most end of the cannula such that each respective needle is oriented toward the fascia surrounding the puncture site in a generally perpendicular orientation. Such needle members, according to said second configuration, are further oriented to extend outwardly from the distal-most end of the cannula by a distance of at least 1.0 cm or greater and pierce through the serous

membrane of various body cavities or tissues such as the pleura and peritoneum, and then the fascia at diametrically opposed points across the puncture, incision, or wound site. To facilitate the ability of the needle/suture complex to gather tissue about a puncture site to form the desired closure, the needle/suture complex will preferably be positioned upon a tapered mount having a generally hourglass shape to thus enable tissue to gather thereabout.

[0011] The needle members are further operative to assume a third retraction configuration whereby each respective tip of the two diametrically-opposed needles are brought into and contained within the distal end of the cannula. To facilitate the ability of the device to assume the third configuration, a grasping mechanism is disposed within the cannula that is operative to grasp each respective needle tip and draw the same back into the cannula. The needle/suture complex is mounted upon a connecting rod disposed within the cannula, which is operative to be advanced downwardly into the cannula such that the needles of the needle/suture complex are deployed through and ultimately retracted back within the lumen of the cannula. When in such third configuration, the device is then withdrawn from the body.

[0012] In use, the suture connected across the respective needles is caused to extend across the puncture site with the free ends thereof being drawn upwardly from the puncture wound as the device is withdrawn from the body, which thus leaves the two ends of the sutures free to be cut away from the needles and then tied down to close the fascial defect. Advantageously, the suture made by the needle/suture complex is positioned such that the suture extends a sufficient diameter from the periphery of the puncture site, in relation to the diameter of the puncture, such that a sufficient amount of tissue is utilized to give strength to the closure. In one embodiment the suture made by the needle/suture complex extends

at least as far away from the periphery of the puncture as the diameter of the puncture. For example, a 5 millimeter diameter puncture is sutured by a needle/suture complex that extend 5 millimeters from the periphery of the puncture. Preferably the suture made by the needle/suture complex is positioned such that the suture extends at least 1 cm or greater across opposed sides of the periphery of the puncture site, such that a sufficient amount of tissue is utilized to give strength to the closure. Additionally, such design advantageously eliminates the need to deploy additional sutures across the suture site, as is necessary with prior art needle passing devices which must be passed multiple times across the puncture wound site. The device further forms a closure in such a manner that the pneumoperitoneum is maintained, thus enabling the device to be utilized without direct visualization with a laparoscope, endoscope, fiberscope, or other similar device.

[0013] Certain embodiments of the present invention provide a fascial puncture site closure device that is capable of forming a closure about a puncture site utilizing a single deployment.

[0014] Another aspect of the present invention provides a fascial puncture site closure device that can form a closure about a puncture site in a manner that minimizes trauma to the patient.

[0015] Another aspect of the present invention provides a fascial puncture site closure device that forms a closure about a puncture site such that the pneumoperitoneum is maintained and the abdominal wall is kept away from the abdominal viscera.

[0016] Another aspect of the present invention provides a fascial puncture site closure device that is capable of being utilized without direct visualization.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] These, as well as other features of the present invention, will become more apparent upon reference to the drawings wherein:

[0018] Figure 1 is a side, partial cross-sectional view of a fascial puncture site closure device constructed in accordance with a preferred embodiment of the present invention.

[0019] Figure 2 is an expanded cross-sectional view of the distal end of the device depicted in Fig. 1.

[0020] Figure 3 is a cross-sectional view of the distal-most end of the device depicted in Figure 2 shown deployed through a puncture site, incision, port, or wound through the skin, subcutaneous fat, fascia, and serous membrane of a body cavity of a patient.

[0021] Figure 4 is a cross-sectional view of the distal end of the device depicted in Figures 2-3 depicting a needle suture complex being deployed through the distal-most end thereof, the needle suture complex assuming an operative configuration for stitching a suture across the puncture site formed within the fascia and serous membrane.

[0022] Figure 5 is a cross-sectional view of the device depicted in Figures 2-4 showing the needle/suture complex extending upwardly into the serous membrane, fascia and subcutaneous fat layers.

[0023] Figure 6 is a cross-sectional view of the device depicted in Figures 2-5, whereby the needles of the needle/ suture structure are shown being captured within the distal end of the device.

[0024] Figure 7 is a cross-sectional view of the device depicted in Figures 2-6 wherein the needles of the needle/suture complex are captured entirely within the distal end of the device as the device is shown being pulled upwardly from the

puncture wound such that the suture of the needle/suture complex remains fixed in position across the puncture site formed through the skin, fascia and serous membrane.

[0025] Figure 8 is a cross-sectional view depicting the placement of the suture following withdrawal of the fascial puncture site closure device from the patient's body.

DETAILED DESCRIPTION OF THE INVENTION

[0026] The detailed description set forth below is intended as a description of the presently preferred embodiment of the invention, and is not intended to represent the only form in which the present invention may be constructed or utilized. The description sets forth the functions and sequences of steps for constructing and operating the invention. It is to be understood, however, that the same or equivalent functions and sequences may be accomplished by different embodiments and that they are also intended to be encompassed within the scope of the invention.

[0027] More specifically, the present invention is directed to a device that is operative to fashion a secure closure or suture of incisions or punctures, in organs, vasculature, and or tissues surrounding a cavity of the body. According to a preferred embodiment, the device comprises an elongate cannula or trocar or other hollow housing member having proximal and distal ends, the latter being configured to be inserted within the body through the puncture and used with a needle/suture complex to perform the closure or suture procedure. The housing cavity may be any shape including but not limited to square, rectangular, or triangular channel. Preferably the housing is tubular or cylindrical in shape. Preferably the size of the cannula and the needle/suture complex is such that the cavity of the body may be

insufflated and or maintained at a desired pressure with the cannula in place and that a suture sufficiently spaced from the edge of the periphery of the puncture may be made with the needle/suture complex to gather the tissue and form the desired closure.

[0028] A fiberscope is a flexible fiberoptic scope which may be used for visualizing tissue, organs, body cavities or vasculature. Endoscopy refers to the visual inspection of any cavity of the body by means of an endoscope. For example, peroral endoscopy is examination of organs accessible to observation through an endoscope passed through the mouth, and transcolonic endoscopy is examination of the colon by means of an endoscope inserted through a trocar or cannula into an incision into the colon wall. A laparoscope is an instrument comparable to an endoscope, and in a laparoscopic procedure is usually inserted into the peritoneal cavity using a cannula or trocar to inspect it. Thoracoscopy is examination of the pleural cavity, also called a plueroscopy, containing or investing the lung and lining the thoracic cavity. Feed tubes or other devices may also be placed or implanted in a body cavity or organ through an incision or trocar puncture. Upon removal, the incision or puncture through which the trocar, tubes, or leads are passed to the cavity or organ may require a suture sufficiently spaced from the edge of the periphery of the feedthrough puncture to gather the tissue and form the desired closure.

[0029] Referring now to the Figures, and initially to Figure 1, there is shown a suture or closure device 10 constructed in accordance with a preferred embodiment of the present invention. As illustrated, the device 10 comprises an elongate cannula or trocar member 12 having proximal and distal ends 12a, 12b, with the distal end 12b being operative for insertion into the patient, and the proximal end 12a having a handle 14 and actuation mechanisms 16, 18 to facilitate handling and operation of the device by a surgeon, discussed more fully below.

[0030] Axially disposed within the lumen of the cannula 12 is an elongate connecting rod 20 having a proximal end 20a that is secured to a trigger mechanism 16 extending outwardly from a position near or upon the proximal end 12a of the cannula 12. As will be appreciated by those skilled in the art, the trigger mechanism 16 cooperates with the handle 14 formed near or upon the proximal end 12a of the cannula 12 to thus enable a surgeon to simultaneously grasp and operate the device 10. The distal end 20b of the connecting rod 20 is coupled to a needle/suture complex 22, more clearly seen in Figure 2, the latter consisting of an opposed pair of angled needle holders 24a, 24b pivotally connected to the connecting rod 20, an opposed pair of angled needles 26a, 26b received within dedicated ones of the needle holders 24a, 24b, and an elongate suture 28 having a first end attached to a respective one of the needles, and the other end attached to the respective other end of the needle. The needle/suture complex 22 will further preferably be positioned upon a tapered mount 30 having a generally hourglass shape to facilitate the ability of the device to form a closure, discussed more fully below, as more clearly seen in Figure 6.

[0031] Additionally provided within the device 10 of the present invention is a needle trap mechanism 32, more clearly depicted in Figure 2, comprised of an elongate cylindrical sleeve axially mounted about a portion of the connecting rod 20. The needle trap includes a proximal end 32a having a handle or other graspable member formed thereon, shown as 18 in Figure 1, the latter extending partially from the cannula member 12 to thus enable a surgeon to manipulate the same. Formed upon the distal end 32b of the needle trap is a generally bell-shaped or frusto-conical shaped housing 34 operative to grasp the tips of the opposed needles 26a, 26b and ultimately contain the same therewithin such that the needles 26a, 26b may ultimately be pulled from their respective needle holders 24a, 24b within which they

are received following deployment of the device 10 and contained within the cannula 12, as discussed more fully below.

[0032] The device 10 of the present invention is specifically configured to be deployed through incisions, wounds, endoscopic, laparoscopic or thorascopic ports, and other such puncture sites in a patient. Preferably the puncture site has a size of at least about10 mm or greater. As will be recognized by those skilled in the art, although certain laparoscopic procedures are performed utilizing laparoscopic ports of less than 10 mm, by far the majority of such laparoscopic, endoscopic or thorascopic procedures rely upon at least one or more larger ports having a size of 10 mm or greater. It should be understood, however, that the present invention could be adapted for deployment through smaller ports, as may be necessary in other applications.

[0033] Referring now to Figure 3, there is shown the distal end of the device 10 depicted in Figures 1-2 shown deployed through the distal end of a puncture, wound, incision, or port and within the abdominal cavity of a patient. The patient may be any mammal or animal in need of closure of a puncture or wound. As discussed above, the distal end of the device 10 will be inserted through a port. The formation of ports or punctures for endoscopic, laparoscopic, and thorascopic procedures is well-known in the arts and utilized extensively in the practice of such surgery. Briefly, such ports are formed via the use of trocars followed by the placement of a port into the patient, the latter defining a channel through which surgical instruments and implants such as tubes, feedthrough for fluids, gases, power, endoscopes, and laparoscopes are deployed for a given surgical procedure. The device 10 of the present invention is specifically used following the surgical procedure to form a closure about the puncture site within the body through which the port was utilized. Initially, the distal end of the device 10 is inserted through the

port such that the distal-most end of the device 10 extends into a body cavity, such as but not limited to the peritoneal cavity or the thoracic cavity, through layers of skin 36, subcutaneous fat 38, fascia 40, and serous membrane 42. The connecting rod 20 is then actuated via the trigger (not shown) such that the connecting rod 20 extends downwardly through the distal end 12b of the cannula 12 such that the needle/suture complex 22 is caused to extend therefrom. As illustrated, the needle/suture complex 22 will be deployed within the body cavity or organ, and beneath the skin 36, subcutaneous fat 38, fascia 40 and peritoneal 42 layers through which the port extends. Puncture sites in body cavities and organs which may be closed by embodiments of the present invention may include but are not limited to the peritoneal cavity, the thoracic cavity, and the colon.

[0034] Once the needle/suture complex 22 is caused to extend through the distal-most end 12b of the cannula 12, the needle/suture complex 22 transitions from its first, folded configuration depicted in Figures 2-3 to a second operative configuration, as illustrated in Figure 4. In such operative configuration, the needle holder arms 24a, 24b pivot outwardly such that the needles 26a, 26b held thereby spread out and extend away from the distal opening of the cannula 12a. To achieve that end, it is contemplated that the needle holder arms 24a, 24b may be outwardly biased via the use of springs or some other biasing force. As illustrated, the needle holder arms 24a, 24b and needles 26a, 26b held thereby are formed to have bends therein to thus enable the needles 26a, 26b to achieve an orientation whereby the needles are positioned in a substantially perpendicular fashion relative to the serous membrane 42 and fascia 40, and generally parallel to the cannula 12 of the device 10. The arms 24a, 24b and needles 26a, 26b are further configured such that the same extend from the distal—most end of the cannula 12 and in diametrically opposed directions from the periphery of the wound, incision, port opening or

puncture site, by a distance sufficient to gather the tissue to form a secure closure. Preferably the distance the needles extend from the periphery of the port or puncture is at least 1 centimeter or greater.

[0035] In this respect, one of the chief advantages of the operation of the device 10 of the present invention is the ability of the same to ultimately stitch a suture into position a sufficient distance about the port opening or periphery to thus cause a more secure closure to ultimately be formed. Prior art devices, in contrast, are incapable of delivering a suture sufficiently across a puncture wound site to fashion a desired secure closure within the patient's body cavity or organ.

[0036] To that end, there is shown in Figure 5 the process by which the suture 28, as deployed by the needle/suture complex 22, is positioned across a puncture site. The opposed needles 26a, 26b extend upwardly and penetrate the serous membrane 42 and fascia 40 in a generally perpendicular fashion and are operative to traverse the serous membrane 42, subcutaneous fat 38 and fascia 40 prior to being captured within the lumen of the cannula 12, discussed more fully below. As will be appreciated, such pathway of penetration defined by the opposed needles 26a, 26b provide for substantially more secure suture placement. To facilitate the ability of the device 10 to form a closure of the puncture site via placement of the suture 28, tapered mount 30 upon which the needle/suture complex 22 is positioned enables tissue to be gathered radially thereabout.

[0037] In order to safely and atraumatically withdraw the needles 26a, 26b deploying the suture 28 about the puncture site, there is further shown in Figure 6 a mechanism by which the present invention operates to accomplish same. As illustrated, the needle/suture complex 22 is operative to assume a third retraction configuration whereby the tips of the respective needles 26a, 26b are captured by the needle trap mechanism 32, and ultimately caused to detach from the respective

needle holders 24a, 24b and remain contained within the cannula 12 of the device 10. Specifically, as the connecting rod 20 is pushed downwardly, the needle holder arms 24a, 24b are forced to rotate inwardly. Such motion consequently causes the needle tips of the opposed needles 26a, 26b to likewise rotate inwardly, such that the tips are received within the capture area 34 formed upon the distal—most end of the needle trap mechanism 32 positioned axially about the connecting rod 20. Once captured, the needle trap mechanism 32, with needle tips captured thereby, is pulled upwardly through the cannula 12 via a lever (i.e., lever 18 in Figure 2) formed on the proximal end thereof extending from the cannula 12 such that each respective needle 26a, 26b is caused to dislodge from the needle holder arm 24a, 24b that it had respectively engaged. As a consequence, the needles 26a, 26b become disengaged from the needle suture complex 22 and are ultimately contained safely within the lumen of the cannula 12.

[0038] As illustrated in Figure 7, as a result of the removal of the needles 26a, 26b from the needle holder arms 24a, 24b, the needles 26a, 26b are caused to advance upwardly through the cannula 12 with the suture ends remaining attached thereto. As will be readily appreciated, by virtue of having been stitched across opposed sides of the incision, wound, port or puncture site, the suture 28 will extend thereacross and upwardly through the piercings made by the respective needles 26a, 26b through the peritoneum 42, fascia 40, fatty tissue 38 and ultimately through the previously formed port channel. As will be appreciated, such suture 28 will be pulled through the body by merely withdrawing the entire device 10 from the patient, as shown in Figure 6.

[0039] Ultimately, the suture 28 will be positioned across the port or puncture site in the manner depicted in Figure 8. As illustrated, the respective ends of the suture 28 will extend outwardly from the body but around the puncture site to

thus fashion a closure of the site. To that end, the suture 28 may be manipulated according to a variety of techniques to thus ensure that the puncture site remains closed thereby.

[0040] Additional modifications and improvements of the present invention may also be apparent to those of ordinary skill in the art. For example, it is contemplated that a variety of mechanisms exist that are capable of capturing needle tips of the needles deployed by the needle/suture complex 22 of the present invention. Additionally, it is contemplated that a variety of needles, needle sizes, and needle/holder configurations may be derived that are capable of causing the needles to ultimately penetrate through the organ tissue, serous membrane, fascia and fatty tissue, in a generally perpendicular orientation, and further are caused to advance through such tissues at a distance sufficient from the periphery of the puncture site sought to be closed. Moreover, a variety of mechanisms may be utilized to deploy the needle/suture complex, which may include a connecting rod configured to retract, twisted or otherwise manipulated to cause the needle/suture complex to transition to its various operative configurations. Thus, the particular combination of parts and steps described, and illustrated herein is intended to represent only certain embodiments of the present invention, and is not intended to serve as limitations of alternative devices and methods within the spirit and scope of the invention.